

Package leaflet: Information for the user

**Boots Thrush Oral Capsule And Cream Duo
(Fluconazole, Clotrimazole)**

Read all of this leaflet carefully before you start using the medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

- 1. What this medicine is and what it is used for**
- 2. What you need to know before you use this medicine**
- 3. How to use this medicine**
- 4. Possible side effects**
- 5. How to store this medicine**
- 6. Contents of the pack and other information**

1. What this medicine is and what it is used for

This pack contains a cream and a single capsule. The cream contains Clotrimazole and the capsule contains Fluconazole. Both of these medicines belong to a group called anti-fungals, which act to treat infections caused by the fungi.

The medicine can be used to treat thrush (vaginal candidiasis) and the external symptoms of thrush (vulval candidiasis). It may also be used by the woman's sexual partner to treat associated penile thrush (candidal balanitis). The capsule can be taken by both men and women, the cream can be used by both partners too. If a woman and her partner both intend to take the capsule you will need one pack each.

Thrush is a common infection caused by a yeast (or fungus), which may live harmlessly in the vagina without you even noticing it. However, in certain circumstances, it may develop into an infection in the vagina and symptoms may spread to the surrounding area. The symptoms may include one or more of the following:

- Itching of the vagina and surrounding area (the vulva)
- Redness and swelling of the tissues of the vagina and vulva.
- Soreness of the vagina and vulva
- A white non-smelling discharge from the vagina.

Thrush may be aggravated by sexual intercourse, but it is not a sexually transmitted disease. Sometimes, however, thrush can be passed to your partner through sexual intercourse.

If your partner has penile thrush he may have one or more of the following symptoms:

- Soreness and redness of the penis
- Tightness of the foreskin
- A white non-smelling penile discharge.

2. What you need to know before you use this medicine

This medicine can be used by adults between the ages of 16 and 60 years. However, some people should not

use this medicine or should seek the advice of their pharmacist or doctor first.

Do not take this medicine:

- If you are allergic to any of the ingredients in the cream or the capsule, or any other anti fungal medicine (you may have had difficulty breathing, rash, swelling of the face, neck, throat or lips)
- If you are taking any of these medicines:
 - Astemizole or terfenadine (for allergy)
 - Pimozide (for mental health conditions)
 - Cisapride (for stomach problems)
 - Quinidine (for heart rhythm problems)
 - Erythromycin (for bacterial infections)
 - Halofantrine (for treatment of malaria)
- If you are pregnant, think you are pregnant, or you are breastfeeding (see “Other important information”)
 - if you are taking amiodarone (used for treating heart problems).

Warnings and precautions

Talk to your pharmacist or doctor:

- If this is the first time you have had these symptoms
- If you have had thrush more than twice in the last 6 months
- If you are under 16 years, or 61 years or older
- If you or your partner have been exposed to a sexually transmitted disease.
- If you have liver disease, or have had unexplained jaundice (yellowing of the skin and eyes)
- If you have kidney problems
- If you have heart problems, including heart rhythm problems, or low levels of potassium, magnesium or calcium in your blood
- If you have AIDS (you may be more likely to experience skin reactions)
- If you have any other long-term illness, or receive regular treatment from your doctor
- If you are taking any other medicines, except for the contraceptive ‘pill’ (see “If you use other medicines” on the back of the leaflet)
- If you have lower stomach pain, or pain or a burning sensation on passing urine.
- If you are unsure about the cause of your symptoms.
- If you are a man and:
 - your sexual partner **does not** have thrush
 - you have an abnormal discharge or leakage from your penis
 - you have sores, ulcers or blisters on your penis
 - your penis has started to smell.
- If you are a woman and:
 - you have any abnormal or irregular vaginal bleeding, or a blood stained discharge
 - you have sores, ulcers or blisters on your vulva or vagina.

Pregnancy and breast-feeding and fertility

Pregnancy: This medicine should not be used if you are pregnant, or if you think you may be pregnant.

Women of childbearing age: You must use a reliable form of contraception when using this medicine. The ingredients in the cream, however, may affect the latex used in barrier contraceptives such as condoms and diaphragms.

You should therefore use other methods of contraception whilst using this medicine for at least 5 days after last using the cream.

Breastfeeding: This medicine should not be used if you are breastfeeding.

Driving and using machines

This medicine is not expected to affect your ability to drive or use machines. However, the medicine may cause dizziness and occasionally fits or other side effects that may affect you. You should not drive or use machines until you are sure you are not affected.

Treating thrush:

You can help the treatment to work if you follow these simple self-help tips:

- Although the infected area will itch, do not scratch as this will damage the surface of the skin and cause the infection to spread further.
- Keep the affected areas of the skin clean
- Pay particular attention to drying the skin but avoid excessive rubbing.

To help prevent thrush from coming back once you have treated it, follow these simple steps:

- Wash daily
- Try to avoid washing with perfumed soaps or using vaginal deodorants
- Do not rub hard with sponges or flannels and avoid hot baths with strong perfumed oils
- Wear cotton underwear and loose fitting clothing. Try to avoid wearing tights, nylon underwear and tight fitting clothing
- After going to the toilet, wipe yourself from the front to the back, as a thrush infection may be transferred from the bowel
- Change your sanitary protection regularly.

Other medicines and Thrush Duo

You should not use this medicine if you are taking certain medicines (see “Do not take”). This medicine may also affect the way other medicines work.

You should talk to your pharmacist if you are taking ANY other medicines, particularly if you are taking any of the following medicines:

- Medicines that thin your blood (e.g. warfarin)
- Rifabutin or rifampicin (for bacterial infections)
- Medicines to reduce cholesterol (e.g. statins)
- Medicines for mental health conditions (tricyclic antidepressants, e.g. amitriptyline, nortriptyline), or for epilepsy (e.g. carbamazepine or phenytoin)
- Methadone (for pain relief or treatment of opioid dependence)
- Fentanyl, alfentanil, or non-steroidal anti-inflammatory medicines (for pain relief or inflammation)
- Medicines for diabetes
- Amphotericin B, voriconazole (for fungal infections)
- Ciclosporin, everolimus, sirolimus, or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)
- Medicines to help you sleep (benzodiazepines e.g. midazolam, triazolam), or for anxiety
- Medicines for high blood pressure (e.g. nifedipine, losartan)
- Medicines for treating cancer e.g. cyclophosphamide or vinca alkaloids)
- Prednisone (a corticosteroid)
- Zidovudine or saquinavir (for HIV infection)
- Theophylline (for asthma)
- Vitamin A
- hydrochlorothiazide (a ‘water pill’).

Any other medicines includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

Thrush Duo contains lactose, Cetyl alcohol and stearyl alcohol

The capsule contains a small amount of lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

Cetyl alcohol and stearyl alcohol in the cream may cause local skin reactions (e.g. contact dermatitis).

3. How to use this medicine

Check the capsule foil is not broken before first use. If it is, do not take that capsule.

Check the cream tube seal is not broken before first use. If it is, do not use the cream.

Pierce tube seal with end of cap.

Age	How much	How often
Adults aged 16 to 60 years	Capsule: One capsule	Once only
	Cream: Apply a thin layer to the affected area	Two or three times a day for 2 weeks

Swallow the capsule with water.

The cream is for use on the skin only. For women, apply the cream to the vulva and surrounding area. For men, apply the cream to the penis.

Do not use for children under 16 years, or if you are an adult of 61 years or older, unless your doctor tells you to.

Do not use more than the amount recommended above.

If symptoms do not go away within 7 days talk to your doctor.

If symptoms clear up but return after 7 days, you can take another capsule, unless you had an allergic reaction the first time.

If you have thrush more than twice in six months you must see your doctor.

If you take more than you should:

Talk to a doctor or go to your nearest hospital casualty department straight away. Take your medicine and this leaflet with you.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of these serious side effects, stop using the medicine. See a doctor at once:

- Difficulty breathing, swelling of the face, neck, tongue or throat, low blood pressure, fainting (severe allergic reactions that may be caused by the capsule or the cream)
- Severe skin rash which may include peeling and blistering of the skin (caused by the capsule).

You must not take fluconazole again if you experience any of these serious side effects.

The capsule may also cause these serious side effects. See a doctor at once if you notice:

- Liver problems such as yellowing of the skin or eyes, dark coloured urine, pale stools, or changes in the way your liver works (that may show up in blood tests)

If you get any of the following side effects see your pharmacist or doctor:

The cream may also cause:

- Irritation, discomfort, pain or a burning or stinging sensation
- Other allergic skin reactions such as itchy rash, swelling, peeling or flaking of the skin, blisters

The capsule may cause:

Common side effects which may affect up to 1 in 10 people:

- Headache, stomach pain, diarrhoea, feeling sick, being sick
- increases in blood tests of liver function, skin rash

Uncommon side effects which may affect up to 1 in 100 people:

- Reduction in red blood cells (anaemia)
- Decreased appetite, feeling very sleepy, difficulty sleeping
- Fits, or convulsions, dizziness, sensation of tingling, pricking or numbness, changes in taste
- Constipation, heartburn, wind, dry mouth, muscle pain
- Liver damage and yellowing of the skin and eyes (jaundice)
- Wheals, blistering (hives), itching, increased sweating
- Extreme tiredness, generally feeling unwell or feeling weak, fever.

Rare side effects which may affect up to 1 in 1,000 people:

- Changes in the blood which may cause unusual bruising or unexplained bleeding and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)
- Low levels of potassium, increased cholesterol or blood fat levels
- Change in the heart rhythm (you may notice an irregular heart rate or beat)
- Liver failure, shaking, hair loss

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Store in the original package.

Use by the date on the end flap of the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

The capsule contains Fluconazole 150mg and the cream contains Clotrimazole 1% w/w, which are the active ingredients.

As well as the active ingredient, the capsule also contains lactose monohydrate, maize starch, sodium laurel sulfate, colloidal anhydrous silica, magnesium stearate. The capsule shell contains titanium dioxide (E171), gelatin, patent blue V (E131), printing ink (containing black iron oxide (E172), propylene glycol (E1520) and shellac glaze). The cream also contains sorbitan stearate, polysorbate 60, cetyl palmitate, stearyl alcohol, cetyl alcohol, 2-octyldodecanol, benzyl alcohol, purified water.

The pack contains one hard blue capsule with FLUCO 150 printed on it, and a 20g tube of white cream.

Marketing Authorisation Holder and Manufacturer

Manufactured for the Boots Company PLC Nottingham NG2 3AA Marketing Authorisation held by Teva UK Limited Eastbourne BN22 9AG

The cream (Boots Thrush 1% w/w Cream) is manufactured by Teva Operations Poland Sp. z.o.o.,ul. Mogilska 80 31-546 Krakow Poland.

The capsule (Boots Thrush Fluconazole 150mg Capsule) is manufactured by Teva Operations Poland Sp. z.o.o.,ul. Mogilska 80 31-546 Krakow Poland.

This leaflet was last revised: October 2015

PL 00289/1476

PL 00289/1477

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA.